



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Imidafenacin

June 3, 2014

Non-proprietary Name

Imidafenacin

Safety measure

Precautions section should be revised in a package insert.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added (underlined parts are revised):

Hepatic dysfunction:

Hepatic dysfunction with elevations of aspartate aminotransferase (AST or glutamate oxaloacetate transaminase [GOT]), alanine aminotransferase (ALT or glutamate pyruvate transaminase [GPT]), or bilirubin may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.